WILLIAMS & CONNOLLY LLP
Douglas R. Marvin (SBN 933671)
Ana C. Reyes (SBN 477354)
725 Twelfth Street, N.W.
Washington, DC 20005
Telephone: (202) 434-5000

Attorneys for Merck Sharp & Dohme Corp.

DLA PIPER LLP (US)
Loren H. Brown (SBN 2533529)
Heidi Levine (SBN 2822740)
Raymond M. Williams (SBN 164068)
1251 Avenue of the Americas, 27th Floor
New York, NY 10020
Telephone: (212) 335-4500

Attorneys for Novo Nordisk Inc.

PEPPER HAMILTON LLP
Nina M. Gussack (SBN 31054)
Kenneth J. King (SBN 1885961)
3000 Two Logan Square East
Eighteenth and Arch Streets
Philadelphia, PA 19103
Telephone: (215) 981-4000

Attorneys for Eli Lilly and Company

O'MELVENY & MYERS LLP
Richard B. Goetz (SBN 115666)
Amy J. Laurendeau (SBN 198321)
4000 South Hope Street
Los Angeles, CA 90071
Telephone: (213) 430-6000

Attorneys for Amylin Pharmaceuticals, LLC

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION

Case No. 13md2452 AJB (MDD)

DEFENDANTS' OPPOSITION TO MOTION TO COMPEL DISCOVERY OF ADVERSE EVENT SOURCE DOCUMENTS AND DATABASES

Judge: Hon. Anthony J. Battaglia
Magistrate: Hon. Mitchell D. Dembin

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

FEDERAL CASES

OTHER AUTHORITIES

INTRODUCTION

There is no dispute that Plaintiffs already have Defendants' adverse event reports. They now move to compel production of the underlying medical and other records of individual patients used to compile those reports ("source files"). They do so on the speculative basis that those files *might* indicate that some of the reports should have been summarized differently. Plaintiffs' request to pursue this unreasonably burdensome fishing expedition should be denied for three reasons.

First, Plaintiffs start their motion by claiming that the Defendants flatly have refused to produce source files. Mot. at 1. That is not true. Defendants offered more than five months ago to produce source files related to the plaintiffs in this litigation. That large sample would have been more than sufficient to accomplish what the MDL Plaintiffs claimed they needed to do—namely, to audit whether the adverse event reports provided to the FDA somehow were inaccurate. Defendants advised the MDL Plaintiffs that, if they were able to identify actual and reasonable concerns from that sample, Defendants then would produce the remaining source files at their own cost. If Plaintiffs could not justify the additional burden of producing additional source files, then Defendants *still would produce* the remaining source files so long as Plaintiffs would agree to bear the cost.

Unlike the JCCP Plaintiffs who have agreed with the Defendants to the production of source files of plaintiffs in that proceeding, the MDL Plaintiffs rejected the proposal. Instead, they insisted on serving a joint motion to compel on Merck, noting that they expected the ruling to apply to all Defendants. The joint motion was fully briefed and ready for Plaintiffs to file in ***March*** 2014, more than five months ago. Merck included, in its part of the brief, its proposal on producing source files. The brief was ready to go. But, then, without giving Merck any explanation, Plaintiffs decided not to file it. Now, five months later, they file essentially the same motion, this time sprinkled with vituperation aimed against all Defendants. Plaintiffs' delay speaks volumes. If source files and database access were truly as important to general

causation as they now claim, Plaintiffs would not have waited months to approach the Court. They would have accepted Defendants' proposal or moved immediately in March and obtained resolution then.

Second, because adverse event reports themselves cannot establish general causation and are irrelevant to preemption, the source files are even less meaningful. At most, adverse event reports in the aggregate may indicate that some issue requires further scientific study, typically by carefully crafted clinical studies or, at least, epidemiology studies. Here, the causal association alleged by Plaintiffs already has been extensively studied—by Defendants, by numerous third-party scientists, and by the FDA. Indeed, given the results of pre-clinical and clinical studies finding no causal link between pancreatic cancer and incretin-based therapies, the FDA publicly has stated that adverse event reports are *not* relevant, much less material, to the question of whether incretin-based drugs cause pancreatic cancer. Thus, even if Plaintiffs could establish that some stray additional adverse events should have been reported differently than Defendants reported them—pure speculation at this point—that fact would not be relevant to preemption because FDA has made clear it will not rely on such reports to assess whether incretin-based drugs cause pancreatic cancer. Production of source files will therefore serve no purpose.

Finally, Plaintiffs' request that Defendants produce "their entire databases" also should be denied. The databases contain information Defendants are precluded by federal law from producing. They are also proprietary to independent vendors and cannot simply be turned over. Defendants produced from their databases adverse event information that was provided to the FDA, omitting fields containing personal health information as required by law. That is all the rules of discovery require.

I. Defendants' Proposed Compromise Addressed Each Party's Respective Concerns and Fairly Allocates the Burden of Production Costs.

In truth, Plaintiffs' purpose is not tied to general causation or preemption. They seek instead to cloud the accuracy of the information Defendants summarize and

report on the MedWatch forms by rooting around in the private medical records of third parties who are unconnected to this litigation. Nonetheless, to avoid further motion practice, Defendants offered a compromise. Defendants offered to produce to Plaintiffs' counsel a sample—namely, the source files related to the adverse event reports of plaintiffs in this litigation—that could be produced without the need to make the same privacy-related redactions that would be required of records relating to third-parties. This is the exact production Plaintiffs' counsel in the parallel JCCP requested and accepted. Plaintiffs then could have reviewed those documents to determine if they could formulate any proper basis for a more expanded production of these materials. If Plaintiffs were unable to establish any such basis, Defendants still would agree to produce source files, so long as Plaintiffs were willing to bear the expense of the review and production.

Notably, since there are hundreds of plaintiffs in this litigation, this would have been a large sample size and was a considerable concession by Defendants. Plaintiffs refused it outright, likely sensing the inevitable conclusion. In an apparent justification for the refusal, Plaintiffs claim that source files for litigants "are usually less informative since they often contain primarily litigation documents." Mot. at 2 n.2. They do not provide any citation for this unadorned assertion and it is, in any event, no answer. The question is not what types of documents are in the source files but, at least according to Plaintiffs, whether they are accurately summarized. Plaintiffs also claim that they need *all* source files because they need to review adverse event reports *in the aggregate*. Mot. at 14. This is perplexing since their motion is premised (albeit incorrectly) on the very opposite assertion—that even one adverse event can create a safety signal. *Id*. at 3.

Plaintiffs claim that Defendants' compromise is illusory because Defendants will simply reject any notion that source files from the sample size provided additional meaningful information. Mot. at 14. Putting aside that the parties have successfully met and conferred on a number of topics, nothing would have prevented Plaintiffs

from seeking relief from the Court if the parties in fact disagreed about the usefulness of the source file samples. At least then the Court and the parties would have been able to have a meaningful discussion based on facts—rather than speculation—as to what the source files purportedly *might* reveal.

II. Production of Irrelevant Adverse Event Reports and Source Files Imposes an Undue Burden on Defendants.

Plaintiffs' motion is based on pure speculation that something in some source file *might* indicate that something in some adverse event report *might* not be fully accurate. In effect, Plaintiffs seek to create a series of mini-trials about whether each adverse event report was accurately summarized and reported to FDA. But whether or not every single adverse event report was fully and accurately reported is irrelevant to general causation or preemption[1] because, as the FDA has expressly stated, adverse event reports themselves *cannot* be used to establish that incretin-based drug use increases the risk of pancreatic cancer. *See infra* pp. 7–8. Thus, even if some adverse event reports might have been summarized differently, that would not change the underlying general causation or preemption analysis.

To clarify the status of the current production, Defendants note that they have voluntarily produced adverse event reports to Plaintiffs.[2] Each Defendant already has

---

[1] Any discovery concerning Plaintiffs' theory that Defendants might have committed fraud on the FDA is irrelevant to conflict preemption. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001). Here, preemption turns on the narrow question of whether the FDA/EMA Assessment, which concludes that the current incretin-based therapies labeling adequately reflects the scientific knowledge regarding pancreatic cancer, *see infra* at pp. 6–8, constitutes "clear evidence that the FDA would not have approved a change" to Defendants' labels to warn that incretin-based therapies are causally associated with an increased risk of pancreatic cancer. *Wyeth v. Levine*, 555 U.S. 555, 571 (2009); *Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1227 (9th Cir.), *vacated sub. nom. L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497 (2011).

[2] Though Defendants maintain that these reports are not relevant to general causation or preemption, Defendants produced them to avoid unnecessary discovery disputes.

produced the following: (1) MedWatch forms and/or adverse event data relating to all pancreatic cancer and pancreatitis adverse events, including clinical and spontaneous, postmarketing adverse event reports in patients using the drugs at issue, ***worldwide***, available to Defendants through February 28, 2014; (2) Defendants' Periodic Adverse Drug Experience Reports (required by FDA) and Periodic Safety Update Reports (required by EMA) (both reports contain information relating to adverse events and are provided as part of the NDA productions); (3) electronic data from Defendants' adverse event reporting databases; and (4) Defendants' standard operating procedures regarding collection and review of adverse event reports. Additionally, at least one 30(b)(6) witness testified about these topics for each of the Defendants. The information Defendants already produced to Plaintiffs communicates all of the medical information that the FDA deems necessary to consider in evaluating adverse events. *See* 21 C.F.R. § 314.80.

A. Adverse Event Reports and Their Attendant Source Files Are Not Relevant to General Causation or Preemption.

1. General Causation.

Plaintiffs' desire to obtain the underlying source files so as to reassess how each adverse event was reported to the FDA would result in a fruitless and burdensome exercise. Even if their experts opined that some reports should have been summarized differently—conclusions that would of course be subject to challenge—the reports cannot establish that incretin-based drugs cause pancreatic cancer.

Courts have recognized that adverse event reports are collected "without any medical controls or scientific assessment," and as a result are "one of the least reliable sources to justify opinions about both general and individual causation." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005).[3] Federal regulations and FDA pronouncements reflect the same understanding. The relevant regulations make

[3] *See also Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 990–91 (8th Cir. 2001); *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995).

clear that an "adverse drug experience" can include "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 314.80(a). And FDA has noted that its adverse event reporting system has "limitations." FDA, *FDA Adverse Event Reporting System (FAERS)*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm (last updated Sept. 10, 2012). Most notably, "there is no certainty that the reported event (adverse event or medication error) was actually due to the product." *Id*.

At most, adverse event reports can alert the FDA and manufacturers that a *potential* causal association exists and that further scientific study is required. Thus, for example, Merck's Head of Global Safety testified in her 30(b)(6) deposition that Merck *does not and cannot* use individual adverse events to assess causation. Rather, at most, adverse event reports can be evaluated *in the aggregate* to *generate hypotheses* that can be tested through more rigorous scientific methods such as clinical trials. Hostelley 30(b)(6) Dep. at 55:5–56:18, 60:11–18 (Mot. Ex. 12). There is no mystery here about the hypothesis, and Plaintiffs certainly do not need source files to state it. The hypothesis is that incretin-based drugs are causally related to pancreatic cancer. But, after rigorous scientific analysis of pre-clinical and clinical studies, the FDA has soundly rejected that hypothesis. *See* Amy G. Egan, et al., *Pancreatic Safety of Incretin-Based Drugs—FDA and EMA Assessment*, 370 New Eng. J. Med. 794 (Feb. 27, 2014) at 2 (online version) ("FDA/EMA Assessment") (Mot. Ex. 8).[4]

[4] Plaintiffs claim that according to the FDA even one adverse event can be viewed as a safety signal. Mot. at 7. That is the rare case. *See* Mot. Ex. 9 ("Usually more than a single report is required to generate a safety signal."). It is also irrelevant here. Generating a safety signal is not proof of causation, it is an indication that further scientific study is required. As stated, that further study has occurred here already. And, FDA has expressly rejected the significance of adverse event report disproportionality—comparing the rate of adverse events reported for the drug to the background rate—in this very context.

2. Preemption.

Source files also have no relevance to the issue of preemption. FDA publicly has stated that adverse event reports are *not* relevant, much less material, to the question of whether incretin-based drugs cause pancreatic cancer. Thus, even if Plaintiffs could establish that some stray additional adverse events should have been reported differently than Defendants reported them—which is pure speculation—that fact would not be relevant to preemption because FDA has made clear that it will not rely on such reports to assess whether incretin-based drugs cause pancreatic cancer.

> In its New England Journal of Medicine assessment, the FDA explained: Both agencies committed themselves to assessing the evidence pertinent to reported adverse events, as well as any factors that might confound safety analysis in the context of antidiabetic drugs. Although the disproportionate reporting of adverse events is commonly interpreted as a safety signal, there are ***inherent limitations*** in the ability to ***establish causal relationships*** [between incretin-based drugs and pancreatic cancer], including the evaluation of events with high background rates, long latency periods, or a possible contribution by the disease itself."

FDA/EMA Assessment at 1 (emphases added). In other words, the very type of "causal" relationship Plaintiffs hope to have their experts opine on based on a review of the adverse event reports and their source files is not possible.

In a related Citizen's Petition, the petitioner relied on the FDA Adverse Event Reporting System database to claim that incretin-based drugs can cause pancreatic cancer. The FDA again expressly rejected that notion: "This conclusion is not supported by the data presented because reporting bias may account for your findings." Mar. 25, 2014 Ltr. from J. Woodcock to E. Barbehenn & S.M. Wolfe at 14 (attached as Ex. A). The FDA went on to discuss at length the limitations of the FAERS database:

> The petition states that Victoza increases the risk of pancreatic cancer and cites AERS data to support this finding. Pancreatic cancer is characterized by the National Cancer Institute as a common cancer, i.e., occurring at a rate of greater than 35,000 new cases per year. Analysis of drug-related risk utilizing FAERS data does not provide strong evidence of risk when the adverse event (i.e., pancreatic cancer) occurs commonly in the background untreated population and has a long latency period.

Id. at 26.

Instead of relying on adverse event reports that cannot establish causation, the FDA has been focused—as Plaintiffs should be—on the science, namely, on the evaluation of more than 250 toxicology studies conducted in nearly 18,000 healthy animals, on 3-month toxicity studies in a rodent model of diabetes, on the independent and blinded examination of more than 120 pancreatic histopathology slides, and, *inter alia*, on pancreatic toxicology studies with exenatide. FDA/EMA Assessment at 1–2. Its analysis also was focused on data from more than 200 clinical trials. *Id.* at 2. As this Court is now aware, based on the ***scientific data***, FDA concluded, "[A]ssertions concerning a causal association between incretin-based drugs and . . . pancreatic cancer, as expressed recently in the scientific literature and in the media, are inconsistent with the current data. . . . [T]he current knowledge [regarding safety risks] is adequately reflected in the product information or labeling."[5] *Id*. at 2.

[5] Plaintiffs grossly take out of context FDA's statement that it will continue to review the safety profiles of these drugs. Mot. at 3 n.3. Indeed, they omit the statement by the EMA and the FDA that the agencies "independently undertook comprehensive evaluations of a safety signal arising from postmarketing reports of pancreatitis and pancreatic cancer in patients using incretin-based drugs" and that their "investigations" are "now complete." The FDA always is reviewing and assessing the safety profiles of drugs. The question for this Court is what the evidence indicates the labeling should reflect now. On that score, the FDA could not have been any clearer.

B. Plaintiffs' Authorities Do Not Support Their Position.

Plaintiffs rely upon a number of authorities they claim support their position. That reliance is misplaced on each count.

1. *This Court's Prior Orders*. The parties never have briefed this issue to the Court. This is the first opportunity Defendants have had to present the considerable authority showing that neither adverse event data nor source files are relevant to the issues currently pending in this litigation. Thus, as Plaintiffs are forced to concede, this Court's statement in June 5, 2014 that source documents for adverse event reports fall within the universe of relevant documents was "quoted [from] Plaintiffs' motion papers," Mot. at 6, and was not based on a review of arguments by both sides on that specific question.

2. *FDA Guidance*. Plaintiffs' motion studiously ignores that the FDA already has assessed the adverse event data in this matter and found that it cannot serve as a basis to establish causation. *See supra* pp. 6–8.

3. *Witness Testimony*. As discussed above, the 30(b)(6) testimony cited by Plaintiffs in context is clear: Defendants do not and cannot use adverse event reports to assess causation. *See supra* p. 6.

4. *Medical Literature*. Plaintiffs claim that "respected scientific journals"—*journals*, plural—"readily connect adverse events to causation." Mot. at 7. Plaintiffs cite only one article, from one journal. That article, dated 1999, does not support their position. It notes, "[p]aradoxically, surveillance systems with good adverse event reporting rates increase the probability of receiving spurious ADR reports when the incidence of the complaint in the overall population is not too rare." Timothy Brewer & Graham A. Colditz, *Postmarketing Surveillance and Adverse Drug Reactions: Current Perspectives and Future Needs*, 281 J. Am. Med. Ass'n 824, 827 (1999)

"the current knowledge is adequately reflected in the product information or labeling." FDA/EMA Assessment at 2.

(Mot. Ex. 11). Even if it did, the fifteen-year-old article hardly trumps the FDA's pronouncement of this year that adverse event data cannot be used in this matter to assess whether incretin-based drugs cause pancreatic cancer.

5. Other Legal Authority. Plaintiffs argue that adverse event reports are "frequently utilized by experts in rendering scientific opinions," and thus, the underlying source files must be produced. Mot. at 7 (quoting *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003)). The quote in *PPA* refers to non-epidemiological data generally, not adverse event reports, specifically. *PPA*, 289 F. Supp. 2d at 1242. The court merely concluded that the expert's consideration of adverse event reports among several other forms of non-epidemiological evidence and an epidemiological study did not itself require disqualifying the expert's testimony. *Id.* There is no indication that the expert considered any adverse event source files produced in discovery. *Id.* Similarly, in *McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092 (D. Or. 2010), the "case reports" experts considered were published articles or abstracts, not source files defendants were compelled to review, redact, and produce in litigation. *Id.* at 1112–14.

6. *Other Litigations*. Plaintiffs' primary contention is that source files are "routinely" produced in other litigations and, therefore, should be produced here. To the contrary, even when discovery is not limited to general causation and preemption as it is here, courts do not "routinely" order production of source files in the volume Plaintiffs seek. For example, in *McClain v. Hoffman-LaRoche, Inc.*, Cause No. IP 02-944-C (S/M) (S.D. Ind. Jan. 13, 2004), the district court was "unconvinced that the likely relevance of this potential information is sufficient to outweigh the defendants' burden of redacting and producing" source files after reviewing a selection of source files *in camera* and comparing them to the MedWatch forms that had already been produced. Ex. B at 2. The court therefore "ordered that the production should go forward, but at the plaintiffs' expense." *Id*.

Other cases Plaintiffs cite also belie Plaintiffs' broad request. In *Chantix* the parties agreed after extensive negotiations that Pfizer would produce source files related to approximately 380 adverse event reports, i.e., less than 5 percent of the total adverse events produced in that litigation. Pfizer subsequently agreed to provide access in a secured location to a broader set of electronically available source files, but Plaintiffs' counsel never pursued them (perhaps indicating they were not critical to their claims). More recently, on August 4, 2014, the *Lipitor* MDL court rejected the plaintiffs' request for broad disclosure of source files, instead ordering Pfizer to produce just 25 source files, with the possibility of producing more if the plaintiffs could demonstrate that the burden of production was sufficiently justified. *See* Case Mgmt. Order No. 14, *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No. 2:14-mn-02502-RMG (D.S.C. Aug. 14, 2014) (attached as Ex. C).

Here, Defendants offered Plaintiffs much more than permitted in the very cases they cite. They offered to produce Plaintiffs' source files at no cost and to produce further source files at Defendants' expense if the sample source files indicated that they in fact provided added benefit. Plaintiffs rejected this compromise.

C. Production of Source Files Will Be Burdensome and Expensive.

Identifying, pulling, and producing adverse event report source material is a time-consuming and burdensome process. Each source material for each adverse event report must be manually pulled from a database. And it is not readily possible to determine the volume of records related to any given report without individually pulling the source materials for that report. Further, any adverse event source material found must be reviewed page by page to redact patient and reporter identifying information, information that pervades such files.[6] The need to redact such information is particularly acute here, since Plaintiffs' stated reason for seeking the

[6] *See, e.g.*, 21 C.F.R. § 20.63(f).

files is to root around in the private medical files of individuals who have no relationship to this litigation.

To exacerbate the problem, Plaintiffs have not limited their motion to source files residing in Defendants' centralized databases. In their draft order they ask this Court to rule that, "[t]o the extent that any of the adverse event source documentation for its incretin medication pancreatic cancer adverse events is not included in its safety databases, each Defendant shall also produce that documentation to Plaintiffs." Mot. at Proposed Order. Source files not necessarily located in the databases include files for foreign adverse event reports, which can be stored in Defendants' foreign offices throughout the world. Many of those source files will be in other languages and subject to the privacy laws of other jurisdictions, compounding the review, redaction, and production burden.[7]

It is easy enough for Plaintiffs to claim that pulling, reviewing, redacting, and producing source files is no "undue" burden, given that they are not the ones doing or paying for any of the work. Mot. at 9–10. But Plaintiffs became remarkably silent when Defendants proposed a cost-shifting procedure that would have put the onus on them to pay for the source files productions *if they could not show from the sample that the source files provided additional, meaningful information*. If, as Plaintiffs claim, it will take "very little time and effort to produce th[e] files," Mot. at 10, Plaintiffs would have readily accepted that offer.

[7] Plaintiffs correctly note that when the parties briefed this issue in March, Merck estimated that production of the source files would require expenditure of "between $280,000 and $400,000" in attorney time and cost. Mot. at 14. Plaintiffs now complain that Merck "greatly inflated the estimate" by including source file page counts for pancreatitis and pancreatic cancer events. Mot. at 15. Because Plaintiffs were then seeking to compel source files for pancreatitis and pancreatic cancer, Merck did not inflate anything. Indeed, the estimate may now be even higher because Plaintiffs now assert that they *also* want source files located outside Defendants' centralized safety databases, including those that may be outside the United States.

Finally, Plaintiffs claim that because Defendants make "billions of dollars from the sale of the very drugs involved in this case" somehow Defendants are not entitled to the proportionality protections afforded litigants by the Federal Rules of Civil Procedure. Mot. at 10. That is not the law. Clarifying just this point, the Committee on Rules of Practice and Procedure recently reiterated in a report to Congress that "consideration of the parties' resources does not . . . justify unlimited discovery requests addressed to a wealthy party." Proposed Amendments to the Federal Rules of Civil Procedure at 22 (May 2014) (attached as Ex. D). Simply put, it is not open discovery season on pharmaceutical companies.

III. Defendants Cannot Produce "Databases."

Plaintiffs accuse Defendants of failing to produce "full and functional versions of their safety databases." Mot. at 11. This complaint is not entirely clear. Defendants already have produced to Plaintiffs the information related to pancreatitis and pancreatic cancer adverse events from their safety databases. They have produced this information in searchable, electronic format, removing information only to comply with privacy regulations.[8] Defendants produced this information in different formats, depending on the Defendant and their adverse event system. Merck, whose database production Plaintiffs specifically criticize, produced information directly from its safety database in the same "quasi-native," industry standard format in which it provides adverse event data to FDA.[9] Merck produced the information in a Microsoft Access database format and also offered to make it available in Excel format.

Plaintiffs apparently want this Court also to order Defendants to provide Plaintiffs with a specific platform to review this information. But such a request is not

[8] Defendants' adverse event productions are described in responses to Request No. 39. Merck RFP Resps. (Mot. Ex. 1) at 30; Amylin RFP Resps. (Mot. Ex. 2) at 53–55; Lilly RFP Resps. (Mot. Ex. 3) at 35; Novo RFP Resps. (Mot. Ex. 4) at 37–38.

[9] *See* Merck RFP Resps. at 3–4.

supported by the Rules. Just because Defendants produce Word documents, for example, they are not required to buy for Plaintiffs software packages or computers to review them on. Defendants do not own the rights to the database platforms, but rather purchase licenses to use them from third parties and therefore cannot legally provide copies of them to Plaintiffs.

There are further problems. Defendants' databases contain information on all of Defendants' products respectively and contain privacy information Defendants are precluded by law from producing. Defendants therefore cannot produce the databases in the format Plaintiffs hypothesize. Nor are they required to do so. Ultimately, there is no requirement that the non-proprietary production afford the same user experience as the proprietary database, so long as the produced version has the "same general capabilities" as the proprietary database. Case Mgmt. Order No. 17, at 2, *In re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig.*, No. 3:12-md-02385-DRH-SCW (S.D. Ill. Jan. 2, 2013) (Mot. Ex. 18); *see also* Lopez Decl. (Mot. Ex. 6) ¶ 17 (Lopez Decl.) (quoting the *Pradaxa* order). That is the case here.

Plaintiffs acknowledge this. In one sentence they concede that producing (1) a "non-proprietary form of [the] native database" (2) without the "database fields with personal identifiers" is appropriate. Mot. at 13. That is precisely what Defendants did —provided information in a electronic format without including fields that contain personal identifiers. Inexplicably, however, in the next sentence Plaintiffs fault Defendants for "extract[ing information from their proprietary databases] in a non-native format" and (2) "delet[ing] personal data." *Id*. Plaintiffs seem to fault Defendants for producing exactly what they have asked for.

Glaringly, Plaintiffs' motion also fails to explain any gap between what they want and what Defendants voluntarily have produced. Plaintiffs "question whether the extraction [Defendants provided] would provide their experts with the same sorting, analytical and other capabilities that Merck's experts will have." Mot. at 13. Yet, even though they have had Merck's and Novo's adverse event productions for at

least three months, and have had Amylin and Lilly's database production for at least seven weeks, Plaintiffs have not identified any difficulty in sorting or analyzing the data in the format given to them. And claims about what Defendants' experts may have access to or may at some point in the future do are, to be fair, premature and speculative at best. Defendants' experts will be required to produce a list of the materials they rely on and will be subject to deposition. If Plaintiffs ever identify an actual unfairness, and not purely a hypothetical one, then the parties can take up any issue at that time.

Plaintiffs' remaining complaints about the database production could have been clarified by conferring with Defendants. Plaintiffs contend that they "cannot tell whether all tables and fields in [Merck's] database . . . are contained in the extraction." Mot. at 13. This should not be a source of confusion. Merck made clear in its written responses that it was "excluding fields containing personal identifying information." Merck RFP Resps. at 3–4, 30. If Plaintiffs had further questions about what specific fields Merck extracted, Plaintiffs could have—and frankly before addressing this Court, should have—asked.

As it stands, Plaintiffs have failed to articulate any particular deficiency in Defendants' safety database production, either through the required meet-and-confer process or in their motion to compel. An order compelling production of data from safety databases that has already been produced is therefore unwarranted.

IV. Sanctions Are Not Warranted.

Before Judge Dembin, and now apparently before this Court, Plaintiffs have demanded sanctions in connection with almost every discovery dispute. If Defendants were as quick as Plaintiffs to seek costs, they would be seeking costs for having to brief the same issue twice, five months apart. Disagreement over discovery requests does not indicate that the defending party is acting in bad faith or engaged in sanctionable conduct. It indicates simply that parties on opposing sides do not always agree on the proper scope of discovery.

Dated: August 26, 2014

By: s/ Ana C. Reyes

Attorney for Merck Sharp & Dohme Corp.
E-mail: areyes@wc.com

By: s/ Heidi Levine

Attorney for Novo Nordisk Inc.
E-mail: heidi.levine@dlapiper.com

By: s/ Amy J. Laurendeau

Attorney for Amylin Pharmaceuticals, LLC
E-mail: alaurendeau@omm.com

By: s/ Kenneth J. King

Attorney for Eli Lilly and Company, a Corporation
E-mail: kingk@pepperlaw.com

SIGNATURE ATTESTATION

I hereby certify that authorization for the filing of this document has been obtained from each of the other signatories shown above and that all signatories concur in the filing's content.

s/ Jonathan L. Williams

EXHIBITS – TABLE OF CONTENTS

Exhibit	Description	Page Numbers
A.	Mar. 25, 2014 Ltr. from J. Woodcock to E. Barbehenn & S.M. Wolfe	A18–A55
B.	*McClain v. Hoffman-LaRoche, Inc.*, Cause No. IP 02-944-C (S/M) (S.D. Ind. Jan. 13, 2004)	B56–60
C.	Case Mgmt. Or. No. 14, *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No. 2:14-mn-02502-RMG (D.S.C. Aug. 14, 2014)	C61–C63
D.	Proposed Amendments to the Federal Rules of Civil Procedure (May 2014)	D64–D121